MAY 1 0 2002

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CardioNow
www.cardionow.com

535 Encinitas Boulevard Suite 118
Encinitas, CA 92024

Tel 760.633.9797
Fax 760.633.4753

9.0 510(k) Summary

Submitter

CardioNow, Inc.
535 Encinitas Boulevard Suite 118
Encinitas, CA 92024

Contact

Johnny Garza
Tel: 760-633-9797 x500
Fax: 760-633-4753

Device Name

Classification: Class II
Common/usual name: Cardiology archive and review system commonly known as PACS (Picture Archiving and Communications Systems
Proprietary Name: CardioNow Cardiology Wide Area Archive and Retrieval System

Intended Use

The CardioNow Cardiology Wide Area Archive and Retrieval System is intended to collect, archive, and display diagnostic information and images. The intent is to provide long-term archival as well as retrieval of this information to/from Hospital Site Servers and to provide compressed versions of these images to Internet Web Clients.

Device Description

The CardioNow Cardiology Wide Area Archive and Retrieval System consists of: a Hospital Site System, the Internet Data Center, Web Client, and the ClinSend Client. Each Hospital Site System collects, archives, and displays diagnostic information and images. The Hospital Site System maintains the imaging exams and related data for local review. It also formats the data for transfer to the Internet Data Center.

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CardioNow

Comparisons to Predicate Device

The substantially equivalent device is the Siemens ACOM.Web, also marketed as the MagicWeb Cardiac system, FDA 510k number K973131.

In reviewing the comparison between CardioNow's Wide Area Archive and Review System and the predicate device, very little difference can be found. Both systems take DICOM image data from DICOM compliant imaging systems. Both systems archive this data in the DICOM format and provide a retrieval function for review. And both systems use a lossy compression technique to provide access to these images over the Internet to users with the appropriate login and password.

The only difference is that the compression technique employed by Siemens is a lossy algorithm following the JPEG standard and the one employed by CardioNow is a lossy algorithm provided by the Apple QuickTime platform, which follows the MPEG-4 standard.

Conclusion

For the acquisition of images from DICOM compliant imaging systems and the conversion of these images using lossy compression for distribution over the Internet, the CardioNow system and the Siemens system use similar techniques and have the same functions. Thus, for DICOM compliant image distribution over the Internet, the CardioNow device is substantially equivalent to the predicate device, the Siemens ACOM.Web.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2002

Mr. Johnny M. Garza
Director, Software Quality Assurance
CardioNow, Inc.
535 Encinitas Blvd., Suite 118
ENCINITAS CA 92024

Re: K020449
Trade/Device Name: CardioNow Cardiology Wide Area Archive and Retrieval System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 4, 2002
Received: February 11, 2002

Dear Mr. Garza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~K003089~~ K020449

Device Name: CardioNow Cardiology Wide Area Archive and Retrieval System

Indications for Use:

The CardioNow Cardiology Wide Area Archive and Retrieval System is intended to collect, archive, and display diagnostic information and images. The intent is to provide long-term archival as well as retrieval of this information to/from Hospital Site Servers and to provide compressed versions of these images to Internet Web Clients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020449